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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

SANDALS, WILLIAM O

ART UNIT PAPER NUMBER

1636

DATE MAILED: 03/11/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/844,508

Applicant(s)
Wolffe et al.

Examiner
William Sandals

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Dec 16, 2002
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-72 is/are pending in the application.
- 4a) Of the above, claim(s) 7, 9, 14-16, 34-42, 71, and 72 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8, 10-13, 17-33, and 43-70 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on Apr 27, 2001 is/are a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8 & 10 6) ☐ Other:

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DETAILED ACTION

Election/Restriction

1. Applicant's election without traverse of Group I, claims 1-6, 8, 10-13, 17-33 and 43-70 in Paper No. 14, mailed December 16, 2002 is acknowledged.
2. Claims 7, 9, 14-16, 34-42 and 71-72 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention of Groups II-X, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 14.
3. Claims 1-72 are pending.

Drawings

4. The drawings as submitted on April 27, 2001, have been approved by the draftsman.

Specification

5. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Double Patenting

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6. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

7. Claims 1-72 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-42 and 44-73 of copending Application No. 10/084,826. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

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F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 1-6, 8, 10-13, 17-33 and 43-70 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 and 17-20 of copending Application No. 09/942,087. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of copending Application No. 09/942,087 are drawn to a method of modulating expression of a gene by contacting the gene with a zinc finger protein which protein comprises a functional domain, wherein the functional domain cause repression or expression of the gene and the functional domain is a chromatin modulating domain. The claims of the instant application are drawn to a method for modulating expression of a gene by contacting the gene with a DNA binding domain (which is claimed in claims 6, 23, 31, 46, 54, 57, 58, 61, 63 and 67 as a zinc finger protein domain) and a chromatin remodeling complex (the chromatin modulating domain of copending

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Application No. 09/942,087 is claimed as a “DNMT” in claim 13, which is defined in copending Application No. 09/942,087 and in the instant application as a functional part of a chromatin remodeling complex). Claims 1-15 and 17-20 of copending Application No. 09/942,087 and claims 1-6, 8, 10-13, 17-33 and 43-70 of the instant application are drawn to overlapping subject matter, and therefore, are obvious one over the other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 1-6, 8, 10-13, 17-33 and 43-70 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 1 and 43 recite “a component of a chromatin remodeling complex or functional fragment thereof”. The claims and specification do not provide adequate written description of “a component of a chromatin remodeling complex or functional fragment thereof”. Non-limiting examples of various species which may be “a chromatin remodeling complex” have been provided in the specification at page

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2, line 20 bridging to page 5, line 6, and at page 6, and at page 24. However, no specific structural identifying features have been described for the genus of chromatin remodeling complexes. Further, no specific biological or chemical characteristics have been provided which describe “a **component** (emphasis added) of a chromatin remodeling complex or functional fragment thereof”. No description has been provided to teach the skilled artisan what constitutes a “component” of a chromatin remodeling complex. Consequently, “a component of a chromatin remodeling complex or functional fragment thereof” may be nothing more than a hydrogen ion, which binds to, and thereby “modifies” a region of chromatin. This being the case, it is not possible to know the function of such an undefined “component”. Consequently, a “functional fragment” is also not defined for the foregoing reasons. Thus, the phrase “a component of a chromatin remodeling complex or functional fragment thereof” is not supported by adequate written description for the term “a component of a chromatin remodeling complex or functional fragment thereof” in the instant claims and specification.

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claims 1-6, 8, 10-13, 17-33 and 43-70 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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14. Claims 1 and 43 recite the term “a component of a chromatin remodeling complex or functional fragment thereof”. A “component of a chromatin remodeling complex or functional fragment thereof” is not defined in the specification or claims. Without proper guidance as to the meaning of the term, one of ordinary skill in the art would not know the metes and bounds of claims 1 and 43, and their dependent claims.

15. Claims 64 and 66 recite “binds to a shared binding site”. No definition of a “shared binding site” has been provided. One of skill in the art would not know if the meaning of the term “shared binding site” refers to chromatin region where two or more genetic elements use the same binding site, or if the meaning may be that two or more genetic elements use “similar” binding sites, although they may be at different locations on a region of chromatin. A third possibility may also exist where the term may include all of the above meanings. The metes and bounds of this term are not defined in the claims and specification. Without proper guidance as to the meaning of the term, one of ordinary skill in the art would not know the metes and bounds of the claim. For the purposes of examination, it is inferred from the text of claim 66 that the meaning of the term “shared binding site” refers to a structure of a chromatin region which is repeated in another location in the chromatin, with the intended meaning being: “binding sites which are identical in their binding characteristics or identical in structure, but being physically separate”.

16. Claims 1 and 43 recite in the preamble of the claims a method of “modifying” chromatin. However, the method steps of the claims recite “binding” a molecule to chromatin. There is no

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nexus between the modifying of the chromatin and the binding of the molecule to the chromatin.

Therefore, the claims are vague and indefinite.

Claim Rejections - 35 USC § 102

17. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

18. Claims 1-6, 8, 10, 12, 13, 17-20, 43-47, 55-57, 59-62, 64-66 and 68-70 are rejected under 35 U.S.C. 102(e) as being anticipated by US 2002/0045158 A1 (Case).

Case teaches at the summary, and paragraphs 0028, 0048, 0081-0100, 0116, 0117, 0124, 0127, 0129 and 0135, a method for modifying a region of interest in cellular chromatin by contacting the chromatin with a fusion molecule (polypeptide) comprising a DNA binding domain and a chromatin remodeling complex protein, thereby modifying the chromatin region of interest and producing an accessible region of the chromatin. The cell may be from a plant, an animal or a human. The chromatin remodeling complex protein may be enzymatic. The fusion molecule may activate or repress gene expression. The fusion molecule may facilitate detection

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of a sequence of interest, which may be a gene. A second molecule may be used in the method. The second molecule may bind to, or modify the chromatin region. The DNA binding domain may be a zinc finger. There may be a library of fusion molecules which may bind various regions of the chromatin and affect expression of more than one gene.

19. Claims 1-6, 8, 12, 13, 17, 43-46, 55, 57, 59-61 and 64-70 are rejected under 35 U.S.C. 102(e) as being anticipated by US 2002/0188103 A1 (Bestor).

Bestor teaches at paragraphs 00060025-0040, 0049, 0053, 0056, 0059 and 0067, a method for modifying a region of interest in cellular chromatin by contacting the chromatin with a fusion molecule (polypeptide) comprising a DNA binding domain and a chromatin remodeling complex protein, thereby modifying the chromatin region of interest and producing an accessible region of the chromatin. The cell may be from a plant, an animal or a human. The chromatin remodeling complex protein may be enzymatic. The fusion molecule may activate or repress gene expression. The DNA binding domain may be a zinc finger. There fusion molecule may bind various regions of the chromatin and affect expression of more than one gene.

Claim Rejections - 35 USC § 103

20. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior

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art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

21. Claims 1-6, 8, 10, 12, 13, 17-33 and 43-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over each of US 2002/0045158 A1 (Case) and US 2002/0188103 A1 (Bestor) in view of US 6,015,709 (Natesan) and US 6,153,383 (Verdine et al.).

The claims are drawn to a method for modifying a region of interest in cellular chromatin by contacting the chromatin with a fusion molecule (polypeptide) comprising a DNA binding domain and a chromatin remodeling complex protein, thereby modifying the chromatin region of interest and producing an accessible region of the chromatin. The cell may be from a plant, an animal or a human. The chromatin remodeling complex protein may be enzymatic. The fusion molecule may activate or repress gene expression. The fusion molecule may facilitate detection of a sequence of interest, which may be a gene. A second molecule may be used in the method. The second molecule may bind to, or modify the chromatin region. The second molecule may be a zinc finger protein, or may comprise a chromatin remodeling complex protein. The DNA binding domain may be a zinc finger. There may be a plurality of fusion molecules which may bind various regions of the chromatin and affect expression of more than one gene.

Each of Case and Bestor teach the invention as described above in the rejection under 35 USC 102.

Each of Case and Bestor did not teach that the second molecule may be a zinc finger protein, or that the second molecule may comprise a chromatin remodeling complex protein, a transcription activator or repressor.

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Nateson teaches at column 2, lines 8-17, column 4, lines 17-44, column 10, line 55 bridging to column 11, lines 34 and column 37, lines 7-55, a fusion protein with a DNA binding domain linked to a transcriptional regulatory domain which modifies a chromatin region to express or repress a gene. There may be a second fusion protein which also binds to and modifies a region of chromatin.

Verdine et al. teaches at, column 2, line 16 bridging to column 3, line 58, column 5, lines 15-55, and column 6, line 7 bridging to column 10, line 27, a fusion protein with a DNA binding domain linked to a transcriptional regulatory domain which modifies a chromatin region to express or repress a gene. There may be a second fusion protein which also binds to and modifies a region of chromatin. There may be a library of first and second molecules which may be a multiplicity of fusion proteins comprising a DNA binding domain and a transcription activating/repressing portion.

It would have been prima facie obvious to one of ordinary skill in the art at the time of filing the instant application to combine the teachings of each of Case and Bestor with the teachings of Natesan and Verdine et al. to produce the instant claimed invention because each of Case, Bestor, Natesan and Verdine et al. teach a fusion protein with a DNA binding domain linked to a transcriptional regulatory domain which modifies a chromatin region to express or repress a gene. The teachings of Natesan and Verdine et al. make it obvious to modify the methods of Case and Bestor to include a second molecule which is a fusion protein with a DNA binding domain linked to a transcriptional regulatory domain which modifies a chromatin region

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affecting expression or repression of a gene because each of Case, Bestor, Natesan and Verdine et al. recite the desirable and beneficial use of a fusion protein with a DNA binding domain linked to a transcriptional regulatory domain to modify a chromatin region which facilitates the expression, repression or detection of a gene in a region of chromatin, and Nateson and Verdine et al. teach the desirable and beneficial use of a second molecule which modifies chromatin.

One of ordinary skill in the art would have been motivated to modify the teachings of each of Case and Bestor with the teachings of Natesan and Verdine et al. to produce the instant claimed invention because each of Case, Bestor, Natesan and Verdine et al. recite the desirable and beneficial use of a fusion protein with a DNA binding domain linked to a transcriptional regulatory domain to modify a chromatin region which facilitates the expression, repression or detection of a gene in a region of chromatin, and Nateson and Verdine et al. teach the desirable and beneficial use of a second molecule which modifies chromatin. Further, a person of ordinary skill in the art would have had a reasonable expectation of success in the producing the instant claimed invention given the teachings of Case, Bestor, Natesan and Verdine et al.

Conclusion

22. Certain papers related to this application are ***welcomed*** to be submitted to Art Unit 1636 by facsimile transmission. The FAX numbers are (703) 308-4242 and 305-3014. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant *does* submit a paper by FAX, the original copy should be retained by the applicant or applicant's representative, and the FAX receipt from your FAX machine is proof of delivery. NO


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DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications should be directed to Dr. William Sandals whose telephone number is (703) 305-1982. The examiner normally can be reached Monday through Thursday from 8:30 AM to 7:00 PM, EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached at (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to the Tech Center customer service center at telephone number (703) 308-0198.

William Sandals, Ph.D.
Examiner
March 6, 2003


REMY YUCEL, PH.D
SUPERVISORY PATENT EXAMINER
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